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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/869,445

Applicant(s)

DUAN, LINGXUN

Examin r

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-49 are pending in the present application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant recites in claim 1, as well as claim 49 that the chimeric protein is "stable." However, Applicant has failed to define the stability of the protein required by the claim. There is no indication as to how long or under what conditions the chimeric protein is "stable."

In claims 1 and 49, Applicant recites the limitation "100-fold sweet as compared to the identical amount of sucrose." This statement is inherently vague and indefinite. Organoleptic qualities such as sweetness require a qualitative determination based on one's senses. Since sweetness is a qualitative determination, it is necessarily vague in nature.

Claims 4, 10, 11, 30, 32 and 33 refer to figures. Generally, it is appropriate to refer to a figure in a claim only when there is no other adequate way of claiming the invention. According to MPEP 2173.05(s):

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by

Art Unit: 1636

reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The present claims are drawn to sequences having 40 percent, 60 percent and 90 percent identity to the amino acid sequences of either the A or B chains of monellin. Moreover, the nucleic acids encoding this wide array of variants also comprise undefined codons which "are

Art Unit: 1636

preferably used by yeast cells.” The instant claims are drawn to sequences with undefined modifications, which have certain activities or functions. According to Applicant’s claims, these sequences comprise a protein that is at least one hundred fold as sweet as sucrose. These are genus claims that encompass a wide array of molecules. The specification does not disclose the wide array of variants or modifications that these claims embrace. The specification also fails to provide any teachings as to how the structures of these sequences relate to their function. Thus, the specification neither describes the complete structure of a representative number of species nor does it describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent of such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed recombinant DNA molecules in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. Courts have recognized the necessity and desirability of permitting an

Art Unit: 1636

applicant for a patent to supplement the written disclosure in an application with a deposit of biological material, which is essential to meet some requirement of the statute with respect to the claimed invention. *Merck and Co., Inc. v. Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *In re Argoudelis*, 434 F.2d 666, 168 USPQ 99 (CCPA 1970).

Applicant claims a vector construct, pGWYS1, in the instant claims. In order to sufficiently enable the claimed vector, Applicant must make a biological deposit. The deposit rules (37 CFR 1.801 - 1.809) set forth examining procedures and conditions of deposit which must be satisfied when a deposit is required. See MPEP 2402-2404.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The present claims are drawn to DNA. The language "DNA" alone ordinarily connotes a product of nature, nucleic acid sequences include exons, introns, regulatory regions etc., which are ordinarily not patentable. The language "isolated DNA," "nucleic acid" or similar such language is preferred.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1636

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 9, 12, 13, 24, 25, 26, 27, 32 and 43-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (U.S. Patent No. 5,478,923).

Kim et al. disclose a nucleic acid encoding a modified monellin that is at least 100 times as sweet as sugar. See column 2. Moreover, Kim et al. disclose that the A and B chains have at least 50% homology and preferably 90% homology with the A and B chains of native monellin. See Column 3. Kim et al. also teach a linking sequence that connects the A and B chains and antibodies to the modified monellin. See Columns 2 and 8. Expression vector comprising promoters and transformants are taught for the expression of the modified monellin. See columns 7 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-23, 27, 31 and 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,627,372) in view of Brierley et al. (U.S. Patent No. 5,324,639) and Sledziewski et al. (U.S. Patent No. 6,300,099).

Art Unit: 1636

Kim et al. is relied upon as described above. Although Kim et al. teach the expression and isolation of modified monellin, they fail to disclose the secretion of modified monellin and isolation in the organisms *Pichia pastoris* or *Saccharomyces cerevisiae*.

Brierley et al. teach the use of *Pichia pastoris* for the production and secretion of proteins. Sledziewski et al. teach *Saccharomyces cerevisiae* used for the production and secretion of proteins. Both references teach the use of constructs comprising signal sequences.

It would have been obvious to one of ordinary skill in the art to use either *Pichia pastoris* or *Saccharomyces cerevisiae* comprising constructs that encode signal peptide sequences to produce monellin as taught by Kim et al. Applicant in the specification admits that "a number of signal sequences have been used to direct secretion of heterologous proteins" in *Pichia pastoris* and *Saccharomyces cerevisiae*. See Specification, page 3. According to MPEP 2129:

When applicant states that something is prior art, it is taken as being available as prior art against the claims. Admitted prior art can be used in obviousness rejections. *In re Nomiya*, 509 F.2d 566, 184 USPQ 607.

On pages 3 through 4 of the specification, Applicant recites many references of prior art relating to the claimed signal sequences and their use to direct secretion of proteins. Therefore, one of skill in the art would have been motivated to use the claimed signal sequences for the production of heterologous proteins in the organisms *Pichia pastoris* and *Saccharomyces cerevisiae* because methods of expressing and isolating proteins using expression constructs comprising signal sequences was well-known in the art. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1636

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
September 22, 2003


JAMES KETTER
PRIMARY EXAMINER